

REMARKS/ARGUMENTS

Claims 15, 21-30 and 32-37 are under examination in the application. The Office Action mailed on May 12, 2009 includes the following objections and rejections:

1. Claim 37 are rejected under 35 U.S.C. § 112, first paragraph, written description.
2. Claims 15, 21-30 and 32-36 are rejected under 35 U.S.C. § 103.
3. Claims 15, 21-30 and 32-37 are rejected under the doctrine of double patenting.

Claim 37 is rejected under 35 U.S.C. § 112, first paragraph, written description.

Applicants respectfully submit that the present application fully supports the use of the transition word “consisting essentially of” in claim 37 and fully complies with 35 U.S.C. § 112, first paragraph. In addition, the skilled artisan would readily understand that the steps of the instant claim includes identifying a human infant suspected of having a translocase deficiency and administering to said human infant a nutritionally effective amount of a compound and one skilled in the art could discern what step would materially alter the method. However, for the sole reason of furthering prosecution Applicants have amended the claim. Applicants respectfully request the Examiner withdraw the rejection under 35 U.S.C. § 112, first paragraph.

Claims 15, 21-30 and 32-36 are rejected under 35 U.S.C. § 103(a).

The Office Action rejects claims 15, 21-30 and 32-36 as unpatentable under 35 U.S.C. § 103(a) over Odle, et al., (Odle) in Journal of Nutrition, 1991, Vol. 121, pp. 605-614 in view of Ajinomoto (Ajinomoto) in JP 52015834A, and Jandacek, et al., (Jandacek) in U.S. Patent No. 4,753,963, and further in view of Kerner, et al., (Kerner) in "Genetic Disorders of Carnitine Metabolism and Their Nutritional Management" in Annual Review of Nutrition, 1998, Vol. 18, pp. 179-206. Applicants respectfully submit that claims 15, 21-30 and 32-36 meet the standard of 35 U.S.C. § 103(a).

The Office Action takes Odle and adds Ajinomoto and Jandacek and Kerner to supposedly teach each and every limitation of the claimed invention. Applicants disagree that the combination of the 4 references fails to comply with the standards of 35 U.S.C. § 103(a). In *KSR Int'l. Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739 (2007), the Court stated that "a patent composed of several elements **is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.** Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a **reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.** This is so because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." *Id.* at 1741 (emphasis added). There is nothing that would lead the skilled artisan to combine Odle and Ajinomoto and Jandacek and Kerner. The Office Action has not provided an adequate reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does and fails to meet the standard of 35 U.S.C. § 103(a).

Moreover, even if there was a motivation to combine Odle and Ajinomoto and Jandacek and Kerner (which there is none) the combination would still fail to teach each and every limitation of the claimed invention and thus fails to meet the standard of 35 U.S.C. § 103(a).

The combination of Odle and Ajinomoto and Jandacek and Kerner fails to teach a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying an infant suspected of having a translocase deficiency; and administering to an infant suspected of having a translocase deficiency a composition comprising a nutritionally effective amount of a n-heptanoic acid to treat the translocase deficiency. Odle may disclose the use of medium-chain triglycerides by neonatal piglets where the chain length of even- and odd-carbon fatty acids and apparent digestion/absorption. Medium-chain triglycerides are not nutritionally effective amount of a n-heptanoic acid. Odle discloses the administering of triglycerides to a pig not identifying an infant suspected of having a translocase deficiency; and administering a composition comprising a nutritionally effective amount of a n-heptanoic acid to treat the translocase deficiency. A medium-chain triglyceride is not a n-heptanoic acid and cannot be

used interchangeably as suggested by the Office Action. Odle fails to teach a method of suppressing the effects of translocase deficiency of a prematurely-born human infant.

The addition of Ajinomoto to Odle does nothing to cure this deficiency, since Ajinomoto discloses (but fails to enable) a food composition having triheptanoin or trinonanoin. Again, there is nothing that relates to the treatment a translocase deficiency in a prematurely-born human infant and nothing that relates to a nutritionally effective amount of a n-heptanoic acid.

Similarly, the addition of Jandacek to Odle and Ajinomoto does nothing to cure this deficiency. Again, Jandacek discloses triglyceride with 3 even numbered carbon chains attached. Specifically, an 18 carbon chain and two 8 carbon chains attached to a glycerol, see Column 4, lines 12-13 of Jandacek. Jandacek does not even teach/enable a triglyceride with an odd carbon fatty acid of seven or less carbons. As a result, the deficiencies in Odle and Ajinomoto are not cured by the addition of Jandacek. The combination still fails to treatment a translocase deficiency in a prematurely-born human infant and discloses nothing that relating to a nutritionally effective amount of a n-heptanoic acid.

The addition of Kerner to Odle and Ajinomoto and Jandacek does nothing to cure this deficiency. Kerner discloses a carnitine disorder that basically functions as an acyltransferase or a carrier for long-chain fatty acids. Kerner does not disclose a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying an infant suspected of having a translocase deficiency; and administering to an infant suspected of having a translocase deficiency a composition comprising a nutritionally effective amount of a n-heptanoic acid to treat the translocase deficiency. In contrast, Kerner relates a carnitine deficiency that results in a deficiency in the transport of long-chain fatty acids.

The combination of Odle and Ajinomoto and Jandacek and Kerner fails to teach every limitation of the instant invention. Specifically, the combination fails to disclose a method of suppressing the effects of translocase deficiency of a prematurely-born human infant by identifying an infant suspected of having a translocase deficiency; and administering to an infant suspected of having a translocase deficiency a composition comprising a nutritionally effective amount of a n-heptanoic acid to treat the translocase deficiency.

Accordingly, claims 15, 21-30 and 32-36 are not rendered obvious by the combination of Odle and Ajinomoto and Jandacek and Kerner. Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. § 103(a).

Claims 15, 21-30 and 32-37 are rejected under the nonstatutory, judicially created doctrine of double patenting over claims 1 and 7 of U. S. Patent No. 6,740,679.

The Office Action states the subject matter claimed in the instant Application is fully disclosed in the patent and is covered by that patent since the patent and the application are claiming common subject matter. A terminal disclaimer in compliance with 37 CFR 1.321(c) will be filed to overcome the rejection based on a nonstatutory double patenting ground provided the conflicting patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

CONCLUSION

In light of the foregoing, Applicants submit that claims 15, 21-30 and 32-37 are in condition for allowance, and an early Notice of Allowance of all pending claims is respectfully solicited.

This paper is being filed with all required fees; however, if any additional fees are necessary the Commissioner is hereby authorized to charge any fees, including those for an extension of time, to Chalker Flores, LLP's Deposit Account No. 50-4863.

If the Examiner has any questions or comments, or if further clarification is required, it is requested that the Examiner contact the undersigned at the telephone number listed below.

Dated: August 12, 2009

Respectfully submitted,

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